AMENDED IN SENATE AUGUST 17, 2004
AMENDED IN SENATE JUNE 28, 2004
AMENDED IN SENATE JUNE 23, 2004
AMENDED IN SENATE SEPTEMBER 8, 2003
AMENDED IN SENATE AUGUST 18, 2003
AMENDED IN SENATE JULY 17, 2003
AMENDED IN ASSEMBLY MAY 20, 2003
AMENDED IN ASSEMBLY MAY 5, 2003
AMENDED IN ASSEMBLY APRIL 24, 2003
AMENDED IN ASSEMBLY MARCH 28, 2003

CALIFORNIA LEGISLATURE—2003-04 REGULAR SESSION

ASSEMBLY BILL

No. 746

Introduced by Assembly Member Matthews (Principal coauthor: Assembly Member Chan)

February 19, 2003

An act to amend Sections 56.05, 56.11, and 56.21 Section 56.05 of the Civil Code, relating to medical information, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 746, as amended, Matthews. Medical information: pharmacies: marketing.

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Existing law prohibits a provider of health care, a health care service plan, contractor, or corporation and its subsidiaries and affiliates from intentionally sharing, selling, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, except as expressly authorized by the patient, enrollee, or subscriber, as specified, or as otherwise required or authorized by law. Violations of these provisions are subject to a civil action for compensatory and punitive damages, and, if a violation results in economic loss or personal injury to a patient, it is punishable as a misdemeanor. Existing law provides that this prohibition also applies to the marketing of medical information, as defined, excluding from the definition of marketing, for these purposes, communications for which the communicator does not receive remuneration from a 3rd party or for specified descriptive purposes, or that are tailored to the circumstances of a particular individual, as specified.

This bill would further exclude from that definition of marketing a written communication that is provided by a pharmacy to a patient that meets specified conditions. The bill would also make related changes.

The bill would declare that it is to take effect immediately as an urgency statute.

Vote: 2/3. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 56.05 of the Civil Code is amended to 2 read:
- 3 56.05. For purposes of this part:

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- (a) "Authorization" means permission granted in accordance with Section 56.11 or 56.21 for the disclosure of medical information.
- (b) "Authorized recipient" means any person who is authorized to receive medical information pursuant to Section 56.10 or 56.20.
- (c) "Contractor" means any person or entity that is a medical group, independent practice association, pharmaceutical benefits manager, or a medical service organization and is not a health care service plan or provider of health care. "Contractor" does not include insurance institutions, as defined in subdivision (k) of

Section 791.02 of the Insurance Code, or pharmaceutical benefits

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managers licensed pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

- (d) "Health care service plan" means any entity regulated pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).
- (e) "Licensed health care professional" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, the Osteopathic Initiative Act or the Chiropractic Initiative Act, or Division 2.5 (commencing with Section 1797) of the Health and Safety Code.
- (f) "Marketing" means to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.

"Marketing" does not include any of the following:

- (1) Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication.
- (2) Communications made to current enrollees solely for the purpose of describing a provider's participation in an existing health care provider network or health plan network of a Knox-Keene licensed health plan to which the enrollees already subscribe; communications made to current enrollees solely for the purpose of describing if, and the extent to which, a product or service, or payment for a product or service, is provided by a provider, contractor, or plan or included in a plan of benefits of a Knox-Keene licensed health plan to which the enrollees already subscribe; or communications made to plan enrollees describing the availability of more cost-effective pharmaceuticals.
- (3) A written communication that is provided to a pharmacy patient during a face-to-face interaction with a pharmacist or with pharmacy personnel, in conjunction with the dispensing of a prescription drug, if all of the following conditions are met:
- (A) The communication, in whole or in part, assists the pharmacy in meeting the goals of Section 601 of Public Law

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104-180 with respect to the transmittal of useful information regarding a prescription drug dispensed to the patient.

- (B) The majority of the communication describes biochemical, pharmacological, or other scientific or health information related to a disease or health condition for which the dispensed drug is indicated, a treatment or therapy for that disease or health condition, or the known sequelae of that disease or condition.
- (C) The pharmacist is available upon request to answer the patient's questions regarding the communication.
- (D) Information that specifically identifies the individual patient, as set forth in 45 C.F.R. 164.514(b)(2)(i)(A) to (Q), inclusive, on December 28, 2000, or any other unique number or code that specifically identifies the individual patient, is not used to determine the sponsored content of the communication.
- (4) Communications that either (A) educate or advise the individual about treatment options for a chronic and seriously debilitating or life-threatening condition, as defined in subdivisions (d) and (e) of Section 1367.21 of the Health and Safety Code, and otherwise maintain the individual's adherence to a prescribed course of medical treatment for the condition, or (B) are part of a disease management program, as defined in Section 1399.901 of the Health and Safety Code, if, under either subparagraph (A) or (B), the health care provider, contractor, or health plan receives direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication, and all of the following apply:
- (i) The individual receiving the communication is notified in the communication in typeface no smaller than 12-point type of the fact that the provider, contractor, or health plan has been remunerated and the source of the remuneration.
- (ii) The individual is provided the opportunity to opt out of receiving future remunerated communications.
- (iii) The communication contains instructions in typeface no smaller than 12-point type describing how the individual can opt out of receiving further communications by calling a toll-free number of the health care provider, contractor, or health plan making the remunerated communications. No further communication may be made to an individual who has opted out

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after 30 calendar days from the date the individual makes the opt out request.

- (g) "Medical information" means any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental or physical condition, or treatment. "Individually identifiable" means that the medical information includes or contains any element of personal identifying information sufficient to allow identification of the individual, such as the patient's name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the individual's identity.
- (h) "Patient" means any natural person, whether or not still living, who received health care services from a provider of health care and to whom medical information pertains.
- (i) "Pharmaceutical company" means any company or business, or an agent or representative thereof, that manufactures, sells, or distributes pharmaceuticals, medications, or prescription drugs. "Pharmaceutical company" does not include a pharmaceutical benefits manager, as included in subdivision (c), or a provider of health care.
- (j) "Provider of health care" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code; any person licensed pursuant to the Osteopathic Initiative Act or the Chiropractic Initiative Act; any person certified pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code; any clinic, health dispensary, or health facility licensed pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code. "Provider of health care" does not include insurance institutions as defined in subdivision (k) of Section 791.02 of the Insurance Code.
- SEC. 2. Section 56.11 of the Civil Code is amended to read: 56.11. Any person or entity that wishes to obtain medical information pursuant to subdivision (a) of Section 56.10, other than a person or entity authorized to receive medical information pursuant to subdivision (b) or (c) of Section 56.10, shall obtain a valid authorization for the release of this information.

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 An authorization for the release of medical information by a provider of health care, health care service plan, pharmaceutical company, or contractor shall be valid if it:

- (a) Is handwritten by the person who signs it or is in a typeface no smaller than 12-point type.
- (b) Is clearly separate from any other language present on the same page and is executed by a signature which serves no other purpose than to execute the authorization.
 - (c) Is signed and dated by one of the following:
- (1) The patient. A patient who is a minor may only sign an authorization for the release of medical information obtained by a provider of health care, health care service plan, pharmaceutical company, or contractor in the course of furnishing services to which the minor could lawfully have consented under Part 1 (commencing with Section 25) or Part 2.7 (commencing with Section 60).
- (2) The legal representative of the patient, if the patient is a minor or an incompetent. However, authorization may not be given under this subdivision for the disclosure of medical information obtained by the provider of health care, health care service plan, pharmaceutical company, or contractor in the course of furnishing services to which a minor patient could lawfully have consented under Part 1 (commencing with Section 25) or Part 2.7 (commencing with Section 60).
- (3) The spouse of the patient or the person financially responsible for the patient, where the medical information is being sought for the sole purpose of processing an application for health insurance or for enrollment in a nonprofit hospital plan, a health care service plan, or an employee benefit plan, and where the patient is to be an enrolled spouse or dependent under the policy or plan.
- (4) The beneficiary or personal representative of a deceased patient.
- (d) States the specific uses and limitations on the types of medical information to be disclosed.
- (e) States the name or functions of the provider of health care, health care service plan, pharmaceutical company, or contractor that may disclose the medical information.
- (f) States the name or functions of the persons or entities authorized to receive the medical information.

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(g) States the specific uses and limitations on the use of the medical information by the persons or entities authorized to receive the medical information.

- (h) States a specific date after which the provider of health care, health care service plan, pharmaceutical company, or contractor is no longer authorized to disclose the medical information.
- (i) Advises the person signing the authorization of the right to receive a copy of the authorization.
- SEC. 3. Section 56.21 of the Civil Code is amended to read: 56.21. An authorization for an employer to disclose medical information shall be valid if it:
- (a) Is handwritten by the person who signs it or is a in typeface no smaller than 12-point type.
- (b) Is clearly separate from any other language present on the same page and is executed by a signature which serves no purpose other than to execute the authorization.
 - (c) Is signed and dated by one of the following:
- (1) The patient, except that a patient who is a minor may only sign an authorization for the disclosure of medical information obtained by a provider of health care in the course of furnishing services to which the minor could lawfully have consented under Part 1 (commencing with Section 25) or Part 2.7 (commencing with Section 60) of Division 1.
- (2) The legal representative of the patient, if the patient is a minor or incompetent. However, authorization may not be given under this subdivision for the disclosure of medical information which pertains to a competent minor and which was created by a provider of health care in the course of furnishing services to which a minor patient could lawfully have consented under Part 1 (commencing with Section 25) or Part 2.7 (commencing with Section 60) of Division 1.
- (3) The beneficiary or personal representative of a deceased patient.
- (d) States the limitations, if any, on the types of medical information to be disclosed.
- (e) States the name or functions of the employer or person authorized to disclose the medical information.
- 38 (f) States the names or functions of the persons or entities authorized to receive the medical information.

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(g) States the limitations, if any, on the use of the medical information by the persons or entities authorized to receive the medical information.

- (h) States a specific date after which the employer is no longer authorized to disclose the medical information.
- (i) Advises the person who signed the authorization of the right to receive a copy of the authorization.

SEC. 4.

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SEC. 2. This act is an urgency statute necessary for the 10 immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

Because of the need to insure continued access to necessary pharmacy services for California residents while maintaining appropriate patient privacy standards, it is necessary for this act to take effect immediately.